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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,816	12/01/2003	Thomas L. Clubb	EV31030US	5558
9561	7590	09/15/2006	EXAMINER	
POPOVICH, WILES & O'CONNELL, PA			MACNEILL, ELIZABETH	
650 THIRD AVENUE SOUTH			ART UNIT	PAPER NUMBER
SUITE 600				3767
MINNEAPOLIS, MN 55402				

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,816	CLUBB, THOMAS L	
	Examiner	Art Unit	
	Elizabeth R. MacNeill	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 August 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6,12-29,33,35-38,42,43,45-53,59-65,69,71 and 72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6,12-29,33,35-38,42,43,45-53,59-65,69,71 and 72 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 December 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/6/06;8/1/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input checked="" type="checkbox"/> Other: <u>2/25/2005;4/27/2005</u> . |

DETAILED ACTION

Election/Restrictions

1. Claims 7-11,30-34,39-41,44,54-58,66-68,70 and 73-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3 August 2006.

Claim Objections

2. Claims 36,43 and 72 objected to because of the following informalities: The use of the word "adjacent" in the claims is unclear. There appear to be two conflicting definitions of the word. Merriam-Webster gives the following: 1. Nearby, 2. Having a common endpoint or border and 3. Immediately preceding or following. The Examiner finds this unclear because "adjacent" encompasses two embodiments: First, where the first and second members are touching and the third member slides between them, and second where they are not touching. In either embodiment, the first and second members are in the same axial arrangement. Examiner suggests the word "abutting" in place of the word "adjacent" to make this distinction more clear. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3,6,12-17,22,23,25,29,33,35-38,42,43,46-50,53,59-65,69,71 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by KUSLEIKA (US #2003/0171770).

Regarding claims 1,3,36,38,42,43,45,50, and 72 Kusleika teaches a catheter comprising a first elongate tubular body (C), a second elongate tubular body (10) and a third elongate tubular body (11) connected by an elongate member (15), wherein the third body is slidable between the first and second bodies, also comprising a guide wire (22) (Fig 1, Fig 4, P0019, P0027, P0028)

- Regarding claims 2, 37, and 49 mechanical stops (57) are used to control the motion of the third body

Regarding claims 6,12,53, and 59 there is a single, cylindrical elongate member.

Regarding claims 13,14,60 and 61 the second member is funnel-shaped

- Regarding claims 15-17 and 62-64, the Examiner takes the "proximal shaft" to be the area of the first member C proximal from the area overlapping with the third member. The proximal shaft is attached to the first body and is made of one cylindrical element.

- Regarding claims 22 and 23, the third member is from 10-40cm in length (P0095)

Regarding claim 25, the second member has a diameter of 2-30mm (P0052)

Regarding claims 29,33,65, and 69 the catheter is an embolic protection catheter (coupled with an embolic filter)

Regarding claims 35 and 71 the tubular members are made of polymers (P0056)

Regarding claims 46, 47 and 48, see the methods described in P0027-P0028 and P0050.

5. Claims 1-3,6,15-17,28,29,33,35-38,42,43,45,47-50,53,59,65,69,71 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by GRIFFIN (US 2003/0125751).

Regarding claims 1,3,36,38,42,43,45,50, and 72 Griffin teaches a catheter comprising a first elongate tubular body (9), a second elongate tubular body (29) and a third elongate tubular body (26) connected by an elongate member (21), wherein the third body is slidable between the first and second bodies, also comprising a guide wire (21) (Fig 6a-6c)

Regarding claims 2, 37, and 49 mechanical stops are disclosed in P0187

Regarding claims 6,12,53, and 59 there is a single, cylindrical elongate member.

Regarding claims 15-17 and 62-64, the Examiner takes the “proximal shaft” to be the area of the first member 9 proximal from the area overlapping with the third member. The proximal shaft is attached to the first body and is made of one cylindrical element.

Regarding claim 28, Griffin teaches that the operating element (third member) has a length of 10-40mm, and is fully outside of the first member. Therefore the distance between the first and second body is between 1 to 10cm. (P0019)

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Regarding claims 29,33,65, and 69 the catheter is an embolic protection catheter (coupled with an embolic filter)

Regarding claims 35 and 71 the tubular members are made of polymers (P0030)

Regarding claims 47 and 48, see the methods described in P0068-P0075

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 4,5,51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin.

Griffin discloses the claimed invention except for the elongate member being one-quarter or less the diameter of the first member. It would have been an obvious matter of design choice to construct these diameters, since the elongate member is disclosed as a guide wire, and the first member is a catheter body, which are generally significantly different in size. Additionally, Griffin discloses that "the cross-sectional area of the operating element being small relative to the cross-sectional area of the catheter shaft" Because the operating element (or second member) is positioned around the elongate member, the elongate member must be even *smaller* than the second member, therefore such a modification would have involved a mere change in the size of a component. A change in size is generally

recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CPA 1955)

8. Claims 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kusleika.

Kusleika teaches the limitations of claim 1 as above, but is silent on the dimensions of his catheter. Kusleika's catheter is designed to be used for the same purpose and in the same manner as the claimed invention (i.e. as an embolic protection device inserted into the artery of a human patient) The application does not disclose any criticality for the dimensions claimed, but does disclose a variety of ranges throughout the specification, including in the applicant's background. It would have been an obvious matter of design choice to create a catheter with the claimed dimensions, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CPA 1955)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Allytt MacNeill
8/21/06

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SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons